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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/435,562	11/08/1999	ERIK J. VAN DER BURG	MVMDINC.001C	5387

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EXAMINER

DAWSON, GLENN K

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 01/30/2004

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/435,562

Applicant(s)

VAN DER BURG ET AL.

Examiner

Glenn K Dawson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-45, 51-98, 101 and 106-109 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-45, 51-98, 101, 106-109 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 20, 21.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Allowable Subject Matter

The indicated allowability of claims in the last office action is withdrawn in view of the newly discovered reference(s) to Banas and Riedy. Rejections based on the newly cited reference(s) follow.

Claim Objections

Claims 38-45 are objected to because of the following informalities: in claim 38, the phrase "the 2nd layer membrane" should be "the 2nd membrane". Appropriate correction is required.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 38-40, 51, 53, 55, 56, 57, 58, 62, 63, 66-69, 72, 75, 83-86, 89, 92, 94, 101, 106 and 109 are rejected under 35 U.S.C. 102(e) as being anticipated by Banas-6124523.

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Banas discloses a device having an expandable stent between two layers of e-PTFE . The layers are bonded together and to the stent by an adhesive layer. The ends of the stent are flared constituting the claimed portions going from a straight configuration to an inclined orientation upon expansion. The porosity of the layers is 10-90 microns.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 61,64,65,70,71,73,74,76,87,88,90,91,93 and 108 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banas, et al.-'523 in view of Huebsch, et al.-'422.

Banas discloses the invention as claimed with the exception of the materials of the layers. Huebsch discloses the use of Nitinol as an expandable frame. It would have been obvious to have manufactured the stent portion of Banas out of nitinol as this material has the required resilience, self-expanding and flexibility that Banas discloses the stent needs. As for the other materials, the specification has not provided any criticality to these materials, has not stated that these choices are designed to solve any particular problem and the examiner contends that the materials of the prior art device would work equally as well, making the claimed materials obvious design choices.

Claims 95-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banas, et al.-'523 in view of Huebsch, et al.-'422 as applied to the claims above, and further in view of Riedy, et al.-5108474.

Banas as modified by Huebsch makes obvious the invention as claimed with the exception of the type of adhesive used. Riedy discloses that polyethylene mesh adhesives were known. It would have been obvious to have used a polyethylene mesh adhesive to attach the layers of Banas's device, as this adhesive has been shown to be effective at forming strong laminates.

Claims 38-45,51-94,101 and 106-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huebsch-'422 in view of Banas, et al.-'523.

Huebsch discloses a device having struts which are bendable to an inclined angle to facilitate their use as a closing device. An outer covering may be applied to the device to improve tissue in-growth. However, the specific material and porosity of the covering is not disclosed.

Banas discloses a device having an expandable stent between two layers of e-PTFE . The layers are bonded together and to the stent by an adhesive layer. The ends of the stent are flared constituting the claimed portions going from a straight configuration to an inclined orientation upon expansion. The porosity of the layers 10-90 microns. It is well known that e-PTFE has a porosity to allow for tissue ingrowth in stents or grafts. See Lentz-'545. It would have been obvious to have provided Huebsch's device with a covering such as that disclosed by Banas, as this is known to provide a good surface allowing for tissue ingrowth.

Claims 95-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huebsch-'422 in view of Banas, et al.-'523 as applied to the claims above, and further in view of Riedy-' et al.-5108474.

Huebsch as modified by Banas makes obvious the invention as claimed with the exception of the type of adhesive used. Riedy discloses that polyethylene mesh adhesives were known. It would have been obvious to have used a polyethylene mesh adhesive to attach the layers of Huebsch and Banas's device, as this adhesive has been shown to be effective at forming strong laminates.

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Response to Arguments

Applicant's arguments with respect to all of the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K Dawson whose telephone number is 703-308-4304. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on 703-308-1957. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Glenn K Dawson
Primary Examiner
Art Unit 3761

Gkd
25 January 2004